

15

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

NAVEED ASLAM,

Defendant.

Case: 2:24-cr-20599

Assigned To : Murphy, Stephen J., III

Referral Judge: Patti, Anthony P.

Assign. Date : 10/23/2024

Description: INDI USA V. SEALED MATTER (NA)

VIO: 18 U.S.C. § 371

21 U.S.C. § 333(a)(2)

21 U.S.C. § 353(c)(3)(A)

21 U.S.C. § 331(t)

**INDICTMENT**

THE GRAND JURY CHARGES:

**General Allegations**

At all times relevant to this Indictment, unless otherwise specified:

**Statutory and Regulatory Background: Food, Drug, and Cosmetic Act**

1. The Food and Drug Administration (“FDA”) was the agency of the United States responsible for regulating the manufacture, labeling, and distribution of drugs in the United States, and protecting the health and safety of the American public. The FDA carried out its responsibilities by enforcing the provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.* (“FDCA”).

2. A “drug” was defined by the FDCA as, among other things, any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; articles (other than food) intended to affect the structure or

any function of the body of man or other animals; and articles intended for use as a component of any such articles. See 21 U.S.C. § 321(g).

3. A “prescription drug” was defined by the FDCA as “a drug intended for use by man which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to administer such drug.” 21 U.S.C. § 353(b)(1)(A). A drug is also a “prescription drug” if the FDA requires it to be administered under the supervision of a practitioner licensed by law to administer such drug as a condition of the FDA’s approval of the drug. 21 U.S.C. § 353(b)(1)(B).

4. The distribution of prescription drugs was regulated by the FDA and was subject to a series of strict controls. The FDCA prohibits “the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 353(c) of this title,” which includes prescription drugs which were purchased by “a public or private hospital or other health care entity.” 21 U.S.C. §§ 331(t) & 353(c)(3)(A).

5. 21 U.S.C. § 353(c)(3)(A) provides, in relevant part, that “[n]o person may sell, purchase, or trade, or offer to sell, purchase, or trade, any drug (i) which is subject to subsection (b), and (ii) (I) which was purchased by a public or private hospital or other health care entity,” subject to limited exceptions in 21 U.S.C. § 353(c)(3)(B).

6. A “health care entity” is defined as: “any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor. Except as provided in § 203.22(h) and (i), a person cannot simultaneously be a ‘health care entity’ and a retail pharmacy or wholesale distributor.” 21 C.F.R. 203.3(q).

### **Selected Relevant Medications**

7. At all times relevant to this Indictment:
- a. Enhertu® was an FDA-approved drug manufactured by Drug Manufacturer 1. It contained the active ingredient trastuzumab deruxtecan and was indicated for treatment of certain types of metastatic breast cancer in adults.
  - b. Padcev® was an FDA-approved drug manufactured by Drug Manufacturer 2. It contained the active ingredient enfortumab vedotin and was indicated for treatment of certain types of bladder cancer and cancers of the urinary tract (renal pelvis, ureter or urethra) that has spread or cannot be removed by surgery in adults.
  - c. Poteligeo® was an FDA-approved drug manufactured by Drug Manufacturer 3. It contained the active ingredient mogamulizumab-kpkc and was indicated for treatment of certain adult patients with Mycosis Fungoides (MF) or Sézary syndrome (SS).
  - d. Tivdak® was an FDA-approved drug manufactured by Drug Manufacturer 4. It contained the active ingredient tisotumab vedotin-tftv and was indicated for treatment of certain adults with cervical cancer.
  - e. Trodelvy® was an FDA-approved drug manufactured by Drug Manufacturer 5. It contained the active ingredient sacituzumab govitecan-hziy and was indicated for treatment of certain adults with particular types of metastatic breast cancer, bladder cancer, or cancer of the urinary tract.

8. Enhertu®, Padcev®, Poteligeo®, Tivdak®, and Trodelvy® were each a “drug” under the FDCA because each was intended for use in the treatment of disease in man. 21 U.S.C. § 321(g)(1)(B).

9. Enhertu®, Padcev®, Poteligeo®, Tivdak®, and Trodelvy® were each a “prescription drug” within the meaning of 21 U.S.C. § 353(b)(1)(A) and (B).

### **The Defendant and Other Relevant Individuals and Entities**

10. NAVEED ASLAM is a resident of West Bloomfield, Michigan and is a licensed medical doctor. At all relevant times he practiced as an oncologist at Somerset Hematology Oncology, P.C. in Royal Oak, Michigan.

11. NAVEED ASLAM and Somerset Hematology Oncology, P.C. were “health care entities” under 21 C.F.R. § 203.3(q) because ASLAM, through Somerset Hematology Oncology, P.C., provided medical treatment to patients.

12. NAVEED ASLAM, through Somerset Hematology Oncology, P.C., had access to several prescription medications through drug distributors.

13. Individual 1 and Individual 2 operated Business-1, a Michigan corporation engaged in business as a retail pharmacy and in the “wholesale distribution” of prescription drugs as defined in 21 C.F.R. § 203.3(cc), (dd).

14. At different times, Business-1 operated out of offices in Troy and Rochester Hills, Michigan, and Business-1 engaged in transactions involving expensive prescription drugs, including oncology drugs.

15. Business-1 and its customers were not “health care entities” under 21 C.F.R. § 203.3(q).

16. Distributor-1 is a publicly traded company that, among other things, distributed prescription drugs to NAVEED ASLAM and Somerset Hematology Oncology, including Enhertu®, Padcev®, Poteligeo®, Tivdak®, and Trodelvy®.

17. In addition to the FDCA’s limits on the distribution of drugs such as Enhertu®, Padcev®, Poteligeo®, Tivdak®, and Trodelvy®, and in general, Distributor-1 limited distribution of Enhertu®, Padcev®, Poteligeo®, Tivdak®, and Trodelvy® to authorized hospitals or health care entities.

**COUNT 1**

**(18 U.S.C. § 371 – Conspiracy to Illegally Sell or Trade Prescription Drugs)**

NAVEED ASLAM

18. The General Allegations are included in this Count.

19. From at least in or around early 2019, and continuing through in or around August 2023, the exact dates being unknown, in the Eastern District of Michigan and elsewhere, the defendant NAVEED ASLAM, did willfully and knowingly, that is, with the specific intent to defraud and mislead and further the object of the conspiracy, combine, conspire, confederate, and agree with others both known and unknown, to illegally sell or trade prescription drugs to or through Business-1 in violation of 21 U.S.C. § 353(c)(3)(A), 21 U.S.C. §§ 331(t), and 333(a)(2).

### **Purpose of the Conspiracy**

20. It was the purpose of the conspiracy for NAVEED ASLAM to unlawfully enrich himself by, among other things, working with others to acquire and illegally sell or trade prescription drugs at a profit.

### **Manner and Means**

21. Before or around early 2019, Individual 1 recruited and came to an agreement with defendant NAVEED ASLAM for him to purchase and acquire expensive prescription drugs—primarily medications that are used to treat cancers – and sell and trade the prescription drugs to and through Business-1 and its customers.

22. Under their agreement, NAVEED ASLAM agreed to use false pretenses to purchase the prescription drugs so that he could sell the drugs at a profit to and through Business-1, and so that Individual 1 and Individual 2 could resell the prescription drugs at a profit.

23. In making such purchases, defendant NAVEED ASLAM made or caused to be made numerous false and misleading statements to Distributor-1, the authorized distributor of the drugs.

24. These false and misleading statements included, but were not limited to, the following:

- a. That NAVEED ASLAM and Somerset Hematology Oncology P.C. purchased prescription drugs and intended to dispense or administer

the prescription drugs he purchased to treat patients pursuant to valid prescriptions; and

- b. That the prescription drugs only would be re-sold in compliance with the law and to be dispensed or administered to patients pursuant to valid prescriptions.

25. By working with NAVEED ASLAM and Somerset Hematology Oncology P.C., Individual 1 and Individual 2 obtained prescription drugs from an authorized distributor that they would not otherwise have been permitted to purchase, and which they were able to sell at a profit through Business-1.

26. From in or about June 2019 through August 2023, defendant NAVEED ASLAM used his medical license and arrangement with Distributor-1 to purchase various prescription drugs. These prescription drugs were prescription medications used to treat cancer, including but not limited to Enhertu®, Padcev®, Poteligeo®, Tivdak®, and Trodelvy®.

27. NAVEED ASLAM then sold and diverted these prescription drugs from the normal pharmaceutical distribution supply chain and distributed them in unauthorized transactions, including further resale to other customers, as described herein.

28. None of the prescription drugs that defendant NAVEED ASLAM purchased with the involvement of Individual 1 and Individual 2 were administered

or intended to be administered to treat patients as required by law and the applicable contract terms with Distributor-1.

29. Instead of using the prescription drugs to treat patients, defendant NAVEED ASLAM sold and transferred the prescription drugs to or through Business-1 with the involvement of Individual 1 and Individual 2.

30. NAVEED ASLAM profited from his purchase and resale of illegally-purchased prescription drugs in at least three ways, depending on the drug: (a) charging Business-1 more than he paid Distributor-1 for the drugs; (b) sharing the profit when Business-1 resold the drugs for more than NAVEED ASLAM charged Business-1 for the drugs; and (c) by receiving rebates and discounts from Distributor-1 based on the amount of qualifying drugs he purchased and resold.

31. In general, the prescription drugs NAVEED ASLAM purchased and resold were shipped to Somerset Hematology, P.C., in Royal Oak, Michigan, and then transferred to Business-1.

32. In general, NAVEED ASLAM notified Individual 1 or Individual 2 after packages of drugs had arrived from distributors including Distributor-1, at which point Individual 1 or Individual 2 either picked up the drugs and transported them to Business-1's offices, or directed others to do so.

33. This transportation arrangement misled Distributor-1, the authorized distributors of the drugs, as to the identity of the actual purchaser of the prescription drugs and the fact that the prescription drugs were not being dispensed to patients,



were being resold at a profit, and therefore did not fall within the limited exceptions to 21 U.S.C. § 353(c)(3)(A) set forth in subsection (B).

34. After the prescription drugs arrived at the offices of Business-1, Individual 1 and Individual 2 directed and controlled the repackaging and redistribution of the prescription drugs to others.

### **Overt Acts**

35. In furtherance of the conspiracy and to accomplish its objects and purpose, ASLAM and his co-conspirators committed or caused to be committed in the Eastern District of Michigan, and elsewhere, at least one of the following overt acts, among others:

36. On or about December 9, 2019, defendant NAVEED ASLAM and Somerset Hematology Oncology, P.C. purchased from Distributor-1 via false and fraudulent statements 42 units of Poteligeo® 20mg/5ml for about \$159,180.00, which he then sold to or through Business-1 for about \$184,800.

37. On or about January 28, 2020, defendant NAVEED ASLAM and Somerset Hematology Oncology, P.C. purchased from Distributor-1 via false and fraudulent statements 21 units of Poteligeo® 20mg/5ml for about \$80,783.85, which he then sold to or through Business-1 for about \$93,975.

38. On or about April 5, 2021, defendant NAVEED ASLAM and Somerset Hematology Oncology, P.C. purchased from Distributor-1 via false and fraudulent

statements 30 units of Trodelvy® 180mg for about \$61,564.50, which he then sold to or through Business-1 for about \$102,000.

39. On or about May 17, 2021, defendant NAVEED ASLAM and Somerset Hematology Oncology, P.C. purchased from Distributor-1 via false and fraudulent statements 30 units of Enhertu® for about \$68,514, which he then sold to or through Business-1 for about \$88,500.

40. On or about June 4, 2021, defendant NAVEED ASLAM and Somerset Hematology Oncology, P.C. purchased from Distributor-1 via false and fraudulent statements 30 units of Padcev® 30mg SDV for about \$102,465, which he then sold to or through Business-1 for about \$132,000.

41. On or about July 13, 2021, defendant NAVEED ASLAM and Somerset Hematology Oncology, P.C. purchased from Distributor-1 via false and fraudulent statements 35 units of Padcev® 30mg SDV for about \$119,542.50, which he then sold to or through Business-1 for about \$154,000.

42. On or about July 22, 2021, defendant NAVEED ASLAM and Somerset Hematology Oncology, P.C. purchased from Distributor-1 via false and fraudulent statements 30 units of Enhertu® for about \$69,541.80, which he then sold to or through Business-1 for about \$90,000.

43. On or about October 28, 2021, defendant NAVEED ASLAM and Somerset Hematology Oncology, P.C. purchased from Distributor-1 via false and

fraudulent statements 30 units of Trodelvy® 180mg for about \$63,411.60, which he then sold to or through Business-1 for about \$87,000.

44. On or about September 1, 2022, defendant NAVEED ASLAM and Somerset Hematology Oncology, P.C. purchased from Distributor-1 via false and fraudulent statements 10 units of Tivdak® 1x40mg vial for about \$58,850, which he then sold to or through Business-1 for about \$69,430.

45. On or about January 5, 2023, defendant NAVEED ASLAM and Somerset Hematology Oncology, P.C. purchased from Distributor-1 via false and fraudulent statements 15 units of Tivdak® 1x40mg vial for about \$91,710, which he then sold to or through Business-1 for about \$105,750.

46. During the period from in or about June 2019 through August 2023, defendant NAVEED ASLAM and Somerset Hematology Oncology, P.C. bought from Distributor-1 and re-sold to and through Business-1 more than \$17 million in prescription drugs, which had been purchased in defendant NAVEED ASLAM's name and using his medical license, and he profited more than \$2.5 million from the sales.

All in violation of Title 18, United States Code, Section 371.

**COUNTS 2-11**  
**(21 U.S.C. §§ 333(a)(2), 353(c)(3)(A), 331(t)-**  
**Illegal Sale or Trade of Prescription Drugs)**

NAVEED ASLAM

47. On or about the dates set forth below, in the Eastern District of Michigan, the defendant NAVEED ASLAM, did, with the intent to defraud and mislead, sell and trade to and through Business-1, the following a prescription drugs:

Count	Date (on or about)	Aslam's Purchase of Drug from Distributor-1	Aslam's Sale of Drugs to/through Business-1
2	December 9, 2019	42 units of Poteligeo® 20mg/5ml for \$159,180.00	42 units of Poteligeo® 20mg/5ml for \$184,800.00
3	January 28, 2020	21 units of Poteligeo® 20mg/5ml for \$80,783.85	21 units of Poteligeo® 20mg/5ml for \$93,975.00
4	April 5, 2021	30 units of Trodelvy® 180mg for \$61,564.50	30 units of Trodelvy® 180mg for \$102,000.00
5	May 17, 2021	30 units of Enhertu® for \$68,514.00	30 units of Enhertu® for \$88,500.00
6	June 4, 2021	30 units of Padcev® 30mg SDV for \$102,465.00	35 units of Padcev® 30mg SDV for \$132,000.00
7	July 13, 2021	35 units of Padcev® 30mg SDV for \$119,542.50	35 units of Padcev® 30mg SDV for \$154,000.00
8	July 22, 2021	30 units of Enhertu® for \$69,541.80	30 units of Enhertu® for \$90,000.00
9	October 28, 2021	30 units of Trodelvy® 180mg for \$63,411.60	30 units of Trodelvy® 180mg for \$87,000.00
10	September 1, 2022	10 units of Tivdak® 1x40mg vial for \$58,850.00	10 units of Tivdak® 1x40mg vial for \$69,430.00
11	January 5, 2023	15 units of Tivdak® 1x40mg vial for \$91,710.00	15 units of Tivdak® 1x40mg vial for \$105,750.00

which had been previously purchased by a health care entity, that is, NAVEED ASLAM and Somerset Hematology Oncology, P.C., contrary to 21 U.S.C. § 353(c)(3)(A), and in violation of 21 U.S.C. §§ 331(t) and 333(a)(2).

**FORFEITURE ALLEGATIONS**

**18 U.S.C. § 982(a)(7) and/or 18 U.S.C. § 981(a)(1)(C) with 28 U.S.C. § 2461**

48. The allegations contained in Counts 1 through 11 of this Indictment are re-alleged and incorporated by reference as though fully set forth herein for the purpose of alleging forfeiture against defendant NAVEED ASLAM, pursuant to the provisions of Title 18, United States Code, Sections 982(a)(7), and 981(a)(1)(C) with Title 28, United States Code, Section 2461.

49. Pursuant to Title 18, United States Code, Section 982(a)(7), and/or 981(a)(1)(C) with Title 28, United States Code, Section 2461, upon conviction of the offense set forth in Count 1 of this Information, in violation of 18 U.S.C. § 371, defendant NAVEED ASLAM shall forfeit to the United States any property, real or personal, that constitutes or is derived, directly or indirectly, from the gross proceeds traceable to the commission of the offense.

50. Substitute Assets: If any of the property described above as being subject to forfeiture, as a result of any act or omission of defendant NAVEED ASLAM:

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third party;
- c. has been placed beyond the jurisdiction of the court;
- d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty,

the United States of America shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b)(1).

51. Money Judgment: Upon conviction of the offense set forth in Count 1 of this Information, defendant NAVEED ASLAM shall be ordered to pay the United States a sum of money equal to the total amount of proceeds defendant NAVEED ASLAM obtained as a result of such violation(s).

THIS IS A TRUE BILL

s/GRAND JURY FOREPERSON

DAWN N. ISON  
United States Attorney

s/MARK CHASTEEN  
Chief, White Collar Crime Unit

s/ANDREW J. LIEVENSE  
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Date: October 23, 2024

**ORIGINAL**United States District Court  
Eastern District of Michigan**Criminal Case Cover Sheet**

Case: 2:24-cr-20599

Assigned To : Murphy, Stephen J., III

Referral Judge: Patti, Anthony P.

Assign. Date : 10/23/2024

Description: INDI USA V. SEALED MATTER (NA)

NOTE: It is the responsibility of the Assistant U.S. Attorney signing this form to complete it.

<b>Companion Case Information</b>	Companion Case Number:
This may be a companion case based upon LCrR 57.10 (b)(4) <sup>1</sup> :	Judge Assigned:
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	AUSA's Initials: <i>AL</i>

Case Title: USA v. NAVEED ASLAMCounty where offense occurred : OaklandCheck One: ☒ Felony ☐ Misdemeanor ☐ Petty

☒ Indictment/\_\_\_ Information --- no prior complaint.  
☐ Indictment/\_\_\_ Information --- based upon prior complaint [Case number: \_\_\_\_\_]  
☐ Indictment/\_\_\_ Information --- based upon LCrR 57.10 (d) [Complete Superseding section below].

**Superseding Case Information**

Superseding to Case No: \_\_\_\_\_ Judge: \_\_\_\_\_

- ☐ Corrects errors; no additional charges or defendants.  
☐ Involves, for plea purposes, different charges or adds counts.  
☐ Embraces same subject matter but adds the additional defendants or charges below:

Defendant nameChargesPrior Complaint (if applicable)

Please take notice that the below listed Assistant United States Attorney is the attorney of record for the above captioned case.

October 23, 2024

Date



Andrew J. Lievense  
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<sup>1</sup> Companion cases are matters in which it appears that (1) substantially similar evidence will be offered at trial, or (2) the same or related parties are present, and the cases arise out of the same transaction or occurrence. Cases may be companion cases even though one of them may have already been terminated.